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Fujifilm Medical Systems, USA

K122454
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FUJIFILM FDR Dual Energy Subtraction (DES) Option 510(k) Summary

Date: August 10, 2012

Contact Person:

Name:	Debbie Peacock
Title:	Regulatory Affairs Manager
Telephone:	(203) 602-3774
Facsimile:	(203) 363-3813

Identification of Device:

Proprietary/Trade Name:	FDR Dual Energy Subtraction (DES) Option
Classification Name:	Stationary X-ray System w/Solid State Imager
Classification:	Panel: Radiology
CFR Section:	21 CFR 892.1650, 21 CFR 892.1680
Product Codes:	KPR/MQB
Common Name:	Stationary X-Ray System

I. INDICATIONS FOR USE

Fujifilm's FDR Dual Energy Subtraction (DES) Option may be used with Fujifilm's DR X-ray Systems and is intended to be used by a qualified/trained doctor or technologist for acquiring dual energy subtraction images of human anatomy.

DES is intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying / overlying anatomical structures.

This device is not intended for mammographic applications.

II. DEVICE DESCRIPTION

Dual Energy Subtraction (DES) is an advanced radiographic imaging application designed as an option to be used with our cleared FDR AcSelerate X-ray system, and will also be used in future FUJIFILM X-ray systems.

Two images are acquired at mutually different X-ray energies. These images are then subject to a weighted subtraction that can remove structures (e.g. soft tissue structures or bone structures) of a specific x-ray absorption characteristic. This results in a completed DES exam that typically consists of three processed images, (1) a standard radiographic image, (2) a soft-tissue image with the bone information removed, and (3) a bone image with the soft tissue information removed.

To suppress involuntary motion artifacts which are typical in dual-exposure energy subtraction, Fujifilm's DES option includes Multi-Stage Registration (MSR) which compensates for involuntary patient motion, such as the patient's heartbeat, that can

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produce slight differences in anatomic registration (seen as artifacts) between the first exposure (high energy image), and the second exposure (low energy image). MSR is added to suppress the motion artifacts seen in the DES image and maintains the image quality.

III. SUMMARY OF STUDIES

System testing was performed and certified to the following International Standards:

- IEC 60601-1: Medical Electrical Equipment-Part 1: General requirements for safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (General)
- UL 60601-1: Medical Electrical Equipment –Part 1: General requirements for safety. 2003
- IEC 60601-1-2: Medical Electrical Equipment-Part 1-2, General requirements for safety-Collateral standard: Electromagnetic compatibility-requirements and tests. 2007.
- IEC 60601-1-3: Medical Electrical Equipment-Part 1, General requirements for safety-3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment. 1994.
- IEC 60601-1-4: Medical Electrical Equipment-Part 1-4; General requirements for safety-Collateral Standard: Programmable Electrical Medical systems. 1996 +A1, 1999.
- IEC 60601-2-7: Medical Electrical Equipment-Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators. 1998.
- IEC 60601-2-28: Medical Electrical Equipment-Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis. 1993.
- IEC 60601-2-32: Medical Electrical Equipment-Part 2: Particular requirements for the safety of associated equipment of X-ray equipment. 1994.
- IEC 60825: Safety of Laser Products-Part 1: Equipment classification and requirements. 2007.
- DICOM V3.0: Digital Imaging and Communications in Medicine (DICOM). 2007.

A literature review was submitted to discuss clinical and phantom studies performed on the outside US version of the proposed device. Studies were performed on the predicate device in Japan. A reading evaluation was performed. Ten radiologists evaluated 20 subject images and concluded that (1) Multi-Stage Registration feature may improve DES detectability of lung nodules in the lower right lung and (2) it has been confirmed by interviews with doctors that the artifact reduction was effective.

Three U.S. clinical DES reference images are included in this submission with and without MSR applied. These images are included to provide a visual demonstration of the effectiveness of Fujifilm's DES with MSR for artifact reduction.

Results of the Software Verification, Validation, bench testing, clinical image samples and literature review support a substantial equivalence determination.

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IV. SUBSTANTIAL EQUIVALENCE

Fujifilm's FDR Dual Energy Subtraction (DES) Option is a modification to our currently-cleared FCR 9501ES (K952862) and is also substantially equivalent to General Electric's Dual Energy and Tissue Equalization Software Options for Digital Radiographic Systems (K013481).

A detailed Substantial Equivalence Comparison is provided in Section 12.

V. CONCLUSION

The proposed optional FDR Dual Energy Subtraction software tested with the currently-cleared FDR AcSelerate System has very similar Indications for Use, Functional and Technical requirements as the currently-cleared General Electric's Dual Energy and Tissue Equalization Software Options for Digital Radiographic Systems (K013481).

The Energy Subtraction algorithm is unchanged from our currently-cleared FCR 9501ES (K952862).

After analyzing bench and certified system test data, as well as literature review and the inclusion of confirmatory images with and without MSR applied, we feel that the proposed and predicate devices can be considered to be as safe and effective as the currently-cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ms. Debbie Peacock
Regulatory Affairs Manager
FUJIFILM Medical Systems, USA, Inc.
419 West Avenue
STAMFORD CT 06902

December 5, 2012

Re: K122454
Trade/Device Name: FUJIFILM Dual Energy Subtraction (DES) software option
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: October 26, 2012
Received: October 31, 2012

Dear Ms. Peacock:

This letter corrects our substantially equivalent letter of November 20, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

FUJIFILM FDR Dual Energy Subtraction (DES) Option

510(k) Number (if known):

Device Name: FUJIFILM FDR Dual Energy Subtraction (DES) Option

Indications For Use:

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This device is not intended for mammographic applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K122454